



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### 45 CFR Parts 160 and 162

[CMS-0053-CN]

RIN 0938-AT38

### **Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard; Correction**

**AGENCY:** Office of the Secretary, Department of Health and Human Services (HHS).

**ACTION:** Proposed rule; correction.

**SUMMARY:** This document corrects technical and typographical errors that appeared in the proposed rule published in the **Federal Register** on December 21, 2022, entitled “Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard.”

**DATES:** The comments due date remains March 21, 2023.

**FOR FURTHER INFORMATION CONTACT:** Geanelle G. Herring, (410) 786-4466 and Christopher Wilson, (410) 786-3178.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

In FR Doc. 2022-27437 of December 21, 2022 (87 FR 78438), there were several technical and typographical errors in the regulations text that are identified and corrected in this correcting document.

#### **II. Summary of Errors**

On page 78453, in the section of the proposed rule that describes the documents that would be incorporated by reference, we inadvertently omitted language regarding the HL7

Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 that we proposed to adopt as the electronic signature standard. Including this implementation guide in the list of documents to be incorporated by reference would align the section with discussion on page 78451, which specifies that the aforementioned implementation guide would be incorporated by reference. This correction does not introduce a new document for incorporation by reference, but, rather, ensures that the proposed incorporation by reference section of the proposed rule identifies all the documents proposed for incorporation by reference. We correct this error in section III. of this document (see item 1).

On page 78468, we note the following:

- In the regulations text for §162.2002, we inadvertently omitted paragraph (f) that identifies the electronic signature standard we proposed to adopt. We also inadvertently omitted §162.920(e)(4), which would specify the incorporation by reference of the implementation guide that would be adopted for the proposed electronic signature standard specified in §162.2002(f). Adding these references would conform the regulations text to the policies proposed on pages 78449 and 78450 where we describe how the term “electronic signature” would be defined, identify the specific electronic signature standard we would adopt, and specify that we would adopt the electronic signature standard at §162.2002(f). These corrections do not introduce new policy proposals in this document, but, rather, conform the regulations text to the policies that were clearly proposed and intended to be reflected in the regulations text. We correct these errors in section III. of this document (see items 2.a. and 1.b.(2)).

- In the regulations text for §162.2002(e)(2), we made an inadvertent typographical error by referencing the wrong citation. We mistakenly referenced 45 CFR 1302(e)(2) rather than 45 CFR 162.1302(e)(2). We correct this error in section III. of this document (see item 2.b.(1)).

### **III. Correction of Errors**

In FR Doc. 2022-27437 of December 21, 2022 (87 FR 78438), make the following

corrections:

1. On page 78453

a. Second column, first full paragraph:

(1) Lines 11 and 12, the phrase “Errata; and (3) HL7 Implementation” is corrected to read “Errata; (3) HL7 Implementation”.

(2) Last line, the phrase “with Errata.” is corrected to read “with Errata; and (4) HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1.”

b. Third column, after the first partial paragraph, the text is corrected by adding a paragraph to read as follows:

“The HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 provides a standardized method of applying Digital Signatures to CDA documents. The standard provides for multiple signers, signers’ declaration of their role, declaration of the purpose of the signature, long-term validation of the Digital Signatures, and data validation of the signed content.”.

2. On page 78468, in the second column, correct § 162.920 by adding paragraph (e)(4) to read as follows:

**§162.920 [Corrected]**

\* \* \* \* \*

(e) \* \* \*

(4) HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 October 2014; IBR approved for §162.2002(f).

3. On page 78468, in the third column, correct § 162.2002 by:

a. In paragraph (e)(2), correcting the reference “45 CFR 1302(e)(2)” to read “45 CFR 162.1302(e)(2)” and

b. Adding paragraph (f).

The addition reads as follows:

**§162.2002 [Corrected]**

\* \* \* \* \*

(f) For transmissions described in §162.2001(a), where a health care provider uses an electronic signature, the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (incorporated by reference, see §162.920).

**Elizabeth J. Gramling**

Executive Secretary to the Department,  
Department of Health and Human Services.

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